



Outcomes of saline implant-based immediate breast reconstruction: 15-year follow-up results

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We sincerely thank Professor Jung-Bok Lee, Division of Biostatistics, Center for Medical Research and Information, Asan Medical Center, University of Ulsan College of Medicine, for support with the statistical analysis and professional advice.

Background Although rarely used at present in South Korea, saline implants accounted for most of the implants used from 1992 to 2007. However, few studies have reported on the long-term outcomes of saline implants, especially in breast reconstruction. We analyzed the long-term outcomes of patients who underwent direct-to-saline implant reconstruction.

Methods This retrospective study included patients who underwent saline implant-based immediate breast reconstruction between 2003 and 2007. The patients' demographic information, medical history, operative/implant details, and oncologic data were collected. Early and late complications, reoperations, and final outcomes of the implant (maintenance, explantation, exchange, and autologous conversion) were analyzed to determine the long-term results and to identify factors affecting the outcomes.

Results Early complications (within 90 days) were noted in 19.5% of patients and late complications (after 90 days) occurred in 29.3% of patients. The most common early complications were skin necrosis and delayed healing, whereas the most common late complications were rippling or visibility and capsular contracture. Of the implants, 22% were replaced (12%) or converted to autologous tissue (10%). The factors that influenced the final outcomes were patient age, nipple-areola-sparing procedure, breast size, implant fill volume, and implant manufacturer.

Conclusions Patients who previously received saline implants still visit the clinic for consultations. This long-term follow-up study with few dropouts reflects the real needs of reconstruction patients. Our results provide useful information for consulting with patients who already have saline implants or those who request for as much information about available implant options as possible.

Keywords Breast implants / Complications / Implant capsular contracture / Mastectomy, subcutaneous

Received: Jul 15, 2020 Revised: Aug 7, 2020 Accepted: Aug 10, 2020
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INTRODUCTION

Since Czerny reported the first successful breast augmentation by transplanting a lipoma from the trunk to the breast in a patient after partial mastectomy, the use of a wide variety of alloplastic materials has been attempted, such as polyurethane, polytetrafluoroethylene (Teflon), and expanded polyvinyl alcohol formaldehyde (Ivalon sponge), ultimately leading to considerable morbidity. Various other materials have also been injected into the breast parenchyma, including epoxy resin, paraffin, petroleum jelly, and liquid silicone [1,2].

The application of modern breast implants as a two-component prosthesis with a shell and gel filler started in 1962, when Cronin and Gerow used silicone gel as a filling material contained within a thin, smooth silicone elastomer shell [3]. Meanwhile, the use of inflatable saline-filled implants to enable a smaller incision was first reported in 1965 [4]. Slight overfilling was recommended to achieve better durability, but led to an unnatural spherical shape, firmness, and scalloping along the implant edge. The consistency was similar to that of water instead of natural breast tissue. Therefore, efforts to develop an implant with a more natural shape and feeling were continued. The first-generation commercial silicone implant by Cronin and Brauer (manufactured by Dow Corning Corp.) contained a thick two-piece silicone elastomer shell with a seam along the periphery. These early implants had a high contracture rate, which encouraged the development of second-generation implants with a thinner, seamless shell with less viscous silicone gel filling. However, the second-generation implants had the drawbacks of gel bleeding and sticky residue within the capsule. Hence, the development of third-generation silicone implants in the 1980s focused on improving implant strength and reducing gel bleeding and implant rupture.

However, the United States Food and Drug Administration (US FDA) called for the temporary restriction of third-generation implants from the market in 1992, stating that there was inadequate information to demonstrate the safety and effectiveness of breast implants. Although medical access to silicone implants continued for selected clinical studies, and the development of fourth- and fifth-generation implants continued, saline-filled breast implants were the only approved implants that most physicians and patients could access until 2006, when the US FDA finally lifted its restrictions on silicone breast implants. Moreover, in Korea, saline implants were the only accessible implants from 1992 to July 2007.

Large-scale follow-up data on silicone implants were published thereafter, and several studies compared the performance, quality of life, satisfaction, and cost-effectiveness of silicone and saline implants [5-8]. However, fewer reports in the literature could be found on the performance and long-term outcomes of saline implants than on those of silicone implants. Clinical surveillance and complication analyses may be less extensive for saline implants because of the perception that they are “safer” than silicone implants. Less attention has also been paid to research and development for newer-generation saline implants after the introduction of form-stable silicone implants. Although it is difficult to determine the exact number of implantations in Korea, it is speculated that many patients underwent breast augmentations and reconstructions with saline implants during the silicone implant moratorium. However, few studies related to saline implants have been published, and only one of them reported long-term outcomes [9-13].

Many patients with saline implants do not seek follow-up implant-related medical care unless they notice deflation of the im-

plant. However, increasing health concerns and press reports of breast implant-associated anaplastic large-cell lymphoma in Korea have raised awareness about the safety and prognosis of breast prostheses of any kind. We aimed to analyze the outcomes of direct-to-implant reconstruction with saline implants between 2003 and 2007 to determine the long-term results and to identify factors affecting the outcomes.

METHODS

This retrospective study included patients who underwent implant-based immediate breast reconstruction with saline implants between May 2003 and March 2007. All patients who were followed up until September 2018 were considered eligible. This study was approved by the institutional review board of the hospital (approval No. 2018-0540).

The patients' demographic information, such as age, body mass index, underlying diseases, and lifestyle variables, including smoking history, was retrieved through a review of their medical records. Operative details (mastectomy specimen weight, implant fill volume, mastectomy technique, lymph node dissection) and oncologic data (cancer stage, preoperative and postoperative adjuvant therapies, subsequent recurrence and management) were also investigated.

Early and late complications, reoperations, and final outcomes of the implants were analyzed. An early complication was defined as any complication that occurred within 90 days after the operation, including infection, delayed wound healing, mastectomy flap skin necrosis, seroma, hematoma, wound dehiscence, and implant exposure. A late complication was defined as any complication that was observed 90 days after the operation, including late infection, late seroma, deflation, malposition, capsular contracture \geq grade 3, unimproved pain, animation, thinning, and rippling or visibility. The final outcome of the implant was categorized as maintenance, explantation, implant change, and autologous (flap) conversion.

Variables were analyzed using the independent t-test or Mann-Whitney test and the chi-square test or Fisher exact test for continuous and categorical variables, respectively. The impact of demographic and perioperative variables on complications and outcomes was analyzed for each implant type. Owing to the small sample size, significance was defined as $P < 0.1$. The statistical analysis was performed using SPSS 24.0 (IBM Corp., Armonk, NY, USA).

RESULTS

A total of 37 patients underwent breast reconstruction with a saline implant in 41 breasts. All implants had a smooth-shell surface. The average age was 34.54 ± 7.99 years (range, 23–53 years) and the average body mass index was 19.68 ± 2.16 kg/m² (range, 16.3–24.3

Table 1. Patients' general demographic characteristics

Variable	Patient (n=37)
Age (yr)	34.54 ± 7.99
Body mass index (kg/m ²)	19.68 ± 2.16
Smoking history	3 (8.11)
Diabetes mellitus	0
Hypertension	1 (2.70)
Pregnancy history	17 (45.95)
Mean follow-up period (mo)	127.03 ± 43.15

Values are presented as mean ± SD or number [%].



Fig. 1. A 28-year-old woman was diagnosed with breast cancer in her left breast. After nipple-sparing mastectomy, the mastectomy specimen weighed 340 g. A 325-mL Mentor saline implant was inserted. The photograph was taken 172 months after the reconstruction. The implant maintained a favorable aesthetic outcome without signs of rupture.

kg/m²). Three patients (8.11%) had a smoking history and one patient (2.70%) had a history of hypertension. None of the patients were diagnosed with diabetes, and 17 patients (45.95%) had a history of pregnancy. The average follow-up period was 127.03 ± 43.15 months (range, 16–175 months) (Table 1).

Mastectomy was performed on the right side in 24 cases (58.54%) and on the left side in 17 cases (41.46%), and nipple-sparing mastectomy was performed in 27 breasts (65.85%). The average mastectomy specimen weight was 289.12 ± 129.13 g (range, 75–555 g) and the average fill volume of the saline implants was 232.44 ± 53.98 cm³ (range, 130–350 cm³). Sentinel lymph node biopsy or axillary lymph node dissection was performed in 23 cases (56.1%), and contralateral augmentation was performed in three patients. Implants manufactured by Allergan (Allergan Inc., Irvine, CA, USA) were used in 11 cases (26.83%) and implants manufactured by Mentor (Mentor Corp., Santa Barbara, CA, USA) were used in 26 cases (73.17%) (Table 2, Fig. 1).

Table 2. Surgical details

Variable	Implants
Reconstruction side	
Right	24 (58.54)
Left	17 (41.46)
Mastectomy type	
Nipple-sparing	27 (65.85)
Skin-sparing	14 (34.15)
Mastectomy weight (g)	289.12 ± 129.13
Implant fill volume (cm ³)	232.44 ± 53.98
Lymph node dissection	
None	18 (43.90)
Sentinel node	12 (29.27)
Axillary node	11 (26.83)
Previous operation	
None	36 (87.8)
Benign mass excision	3 (7.32)
Breast-conserving operation with radiotherapy	2 (4.88)
Bilateral reconstruction	4 (9.76)
Contralateral augmentation	3 (7.32)
Implant manufacturer	
Allergan	11 (26.83)
Mentor	30 (73.17)
Use of ADM	3 (7.32)
Revisory surgery	1 (2.44)

Values are presented as number [%] or mean ± SD. ADM, acellular dermal matrix.

Twenty-one patients were diagnosed with stage 1 cancer (51.22%) and 10 (24.39%) were diagnosed with carcinoma *in situ*. Neoadjuvant chemotherapy was performed in two cases (4.88%) and adjuvant chemotherapy was performed in 15 cases (36.59%). Two patients (4.88%) were treated with breast-conserving surgery and radiation therapy before implant insertion, and postoperative radiotherapy was performed in three cases (7.32%). During the follow-up period, local recurrence occurred in five cases (12.2%) and regional lymph node recurrence took place in three cases (7.32%) (Table 3).

The total number of early complications was eight, including three cases of skin necrosis (7.32%), one case of hematoma (2.44%), and one case (2.44%) of implant exposure due to delayed wound healing, which occurred within 90 days after the operation. Late complications occurred in 12 cases (29.27%). The most frequent late complication was rippling or visibility (six cases, 14.64%), and there were no cases of infection, seroma, or deflation. In addition, capsular contracture ≥ grade 3 (five cases, 12.20%), malposition (four cases, 9.76%), pain (two cases, 4.88%), and thinning (one case, 2.44%) were reported as common chief complaints. Nine of

Table 3. Oncologic information

Variable	No. of implants (%)
Perioperative	
Stage	
<i>In situ</i>	10 (24.39)
1	21 (51.22)
2	7 (17.07)
3	3 (7.32)
Neoadjuvant chemotherapy	2 (4.88)
Adjuvant chemotherapy	15 (36.59)
Preoperative radiotherapy	2 (4.88)
Adjuvant radiotherapy	3 (7.32)
Hormone therapy	19 (46.34)
Follow-up	
Local recurrence	5 (12.20)
Regional (lymph node) recurrence	3 (7.32)
No. of operations for recurrence	
0	36 (87.8)
1	3 (7.32)
2	2 (4.88)
Implant removal owing to recurrence	0

Table 5. Subgroup comparison: early complications within postoperative 90 days

Variable	No complications (n=33)	Any complications (n=8)	P-value
Age (yr)	36.76 ± 9.19	31.63 ± 4.69	0.1362
Body mass index (kg/m ²)	19.77 ± 2.05	19.61 ± 2.39	0.8486
History of pregnancy	16 (48.48)	3 (37.5)	0.7033
Hormone therapy	14 (42.42)	5 (62.5)	0.4362
Previous surgery history	4 (12.12)	1 (12.5)	1.0000
Stage 2 or 3	7 (21.21)	3 (37.5)	0.3780
Skin-sparing mastectomy	14 (42.42)	0	0.0353 ^a
Any lymph node dissection	18 (54.55)	5 (62.5)	1.0000
Implant manufacturer: Allergan	8 (24.24)	3 (37.5)	0.6582
Mastectomy specimen weight (g)	282.7 ± 127.81	315.63 ± 140.01	0.5646
Implant fill volume (cm ³)	232.12 ± 51.16	233.75 ± 68.44	0.9605

Values are presented as mean ± SD or number (%).

^aP < 0.1.

the 41 saline implants were eventually removed. Five implants were exchanged with another implant (12.20%) and four were converted to autologous tissue (9.76%) (Table 4).

When a two-subgroup comparison was conducted according to the occurrence of early complications (within 90 days), skin-sparing mastectomy (vs. nipple-areolar skin-sparing mastectomy) was significantly more common in the group without early complica-

Table 4. Early/late complications and final results

Variable	No. of implants (%)
Early complications	
Any complications within postoperative 90 days	8 (19.51)
Infection	0
Red breast syndrome	0
Skin necrosis	3 (7.32)
Delayed wound healing	5 (12.20)
Seroma	0
Hematoma	1 (2.44)
Dehiscence	0
Implant exposure	1 (2.44)
Late complications	
Any complications after postoperative 90 day	12 (29.27)
Infection	0
Seroma	0
Deflation	0
Malposition	4 (9.76)
Capsular contracture ≥ grade 3	5 (12.20)
Pain	2 (4.88)
Animation	0
Thinning	1 (2.44)
Rippling or visibility	6 (14.63)
Final outcome	
Maintenance	32 (78.05)
Implant change	5 (12.20)
Autologous conversion	4 (9.76)

tions (42.42% vs. 0%, P = 0.0353) (Table 5). Meanwhile, patients with late complications were significantly older than those without late complications (32.66 years vs. 43.25 years, P = 0.0001). Notably, Allergan implants were significantly associated with late complications, as 50% of the implants with complications were made by Allergan, whereas only 17% of the implants without complications were Allergan (P = 0.0522). Implant fill volume also significantly affected the occurrence of late complications (258.33 ± 45.49 cm³ in the group with complications vs. 221.72 ± 54.25 cm³ in the group without complications, P = 0.0427) (Table 6).

Lastly, the final outcomes of the implants were analyzed. Patients whose implants were removed were older (42.44 ± 10.47 years vs. 33.88 ± 7.26 years, P = 0.0073) and were more likely to have an Allergan prosthesis (66.67% vs. 15.63%, P = 0.0058). In addition, the mastectomy specimen was heavier (363.78 ± 128.77 g vs. 268.13 ± 123.14 g, P = 0.0630) and the implant fill volume was larger (268.89 ± 36.55 cm³ vs. 222.19 ± 54.05 cm³, P = 0.0157) in the implant removal group (Table 7). Local recurrence occurred in five cases, which were all indicated for oncologic surgery. All implants were maintained despite local recurrence and subsequent wide excision.

Table 6. Subgroup comparison: late complications after postoperative 90 days

Variable	No complication (n=29)	Any complications (n=12)	P-value
Age (yr)	32.66 ± 6.16	43.25 ± 9.59	0.0001 ^{a)}
Body mass index (kg/m ²)	19.54 ± 2.00	20.33 ± 2.36	0.3086
History of pregnancy	12 (41.38)	7 (58.33)	0.3219
Hormone therapy	14 (48.28)	5 (41.67)	0.6994
Previous surgery history	5 (17.24)	0	0.2979
Stage 2 or 3	6 (20.69)	4 (33.33)	0.4410
Skin-sparing mastectomy	13 (44.83)	1 (8.33)	0.0328 ^{a)}
Any lymph node dissection	17 (58.62)	6 (50.0)	0.6128
Implant manufacturer: Allergan	5 (17.24)	6 (50.0)	0.0522 ^{a)}
Mastectomy specimen weight (g)	270.17 ± 126.51	334.92 ± 129.07	0.1518
Implant fill volume (cm ³)	221.72 ± 54.25	258.33 ± 45.49	0.0427 ^{a)}
Early complications within postoperative 90 days	7 (24.14)	1 (8.33)	0.3984

Values are presented as mean ± SD or number (%).

^{a)}P < 0.1.

DISCUSSION

The use of silicone implants rapidly increased after the US FDA lifted its restrictions, and most aesthetic and reconstructive procedures are currently performed with silicone implants. Especially in postmastectomy breast reconstruction, previous cross-sectional studies showed that patients who received silicone implants reported significantly higher satisfaction and higher quality-of-life scores as measured by the BREAST-Q than those who received saline implants [6,14]. A thorough analysis of the US FDA large post-approval study database was reported in 2019, which enrolled over 90,000 women who received a saline implant or a silicone implant from two manufacturers (Allergan and Mentor) from 2007 to 2010. This prospective cohort study revealed that silicone implants were associated with higher rates of Sjögren syndrome, scleroderma, rheumatoid arthritis, and other morbidities. The rate of rupture was higher for saline implants, and that of capsular contracture was higher for silicone implants. The reoperation rate was 11.7% for primary augmentation and 25% for primary/revision reconstruction at 7 years, which is similar to our reoperation rate (22%) [8].

According to a business report, silicone implants predominated in the United States, with an >80% market share when implants were categorized by the filler material type. However, the proportion of saline implant usage for augmentation/reconstruction cases in 2018 to 2019 remained at about 18% in the United States and 4% in Korea for the Mentor implant (data not shown). Siotos et al. [7] reported that 43% of their patients underwent breast reconstruc-

Table 7. Subgroup comparison: final outcomes

Variable	Implant removal (n=9)	Implant maintenance (n=32)	P-value
Age (yr)	42.44 ± 10.47	33.88 ± 7.26	0.0073 ^{a)}
Body mass index (kg/m ²)	20.06 ± 2.33	19.65 ± 2.05	0.6139
History of pregnancy	4 (44.44)	15 (46.88)	1.0000
Hormone therapy	4 (44.44)	15 (46.88)	1.0000
Previous surgery history	0	5 (15.63)	0.5681
Stage 2 or 3	3 (33.33)	7 (21.88)	0.6622
Skin-sparing mastectomy	1 (11.11)	13 (40.63)	0.1308
Any lymph node dissection	5 (55.56)	18 (56.25)	1.0000
Implant manufacturer: Allergan	6 (66.67)	5 (15.63)	0.0058 ^{a)}
Mastectomy specimen weight (g)	363.78 ± 128.77	268.13 ± 123.14	0.0630 ^{a)}
Implant fill volume (cm ³)	268.89 ± 36.55	222.19 ± 54.05	0.0157 ^{a)}
Early complications within postoperative 90 days	1 (11.11)	7 (21.88)	0.6586
Late complications after postoperative 90 days	0	5 (15.63)	0.5681

Values are presented as mean ± SD or number (%).

^{a)}P < 0.1.

tion with a saline implant between 2010 and 2015. The BREAST-Q-adjusted life-years were 28.11 for saline implants and 23.57 for silicone implants, demonstrating the higher cost-effectiveness of saline implants. The authors suggested that saline implants may be more cost-effective than silicone implants, although the difference was small. The merits and demerits of each implant are clear. Saline implants were never as controversial as silicone gel implants; however, they also have not yielded the same innovations. Several shaped saline implants are now available, although if the main concern is shape and feel, silicone implants would be a better option. If safety and a minimal or remote incision are prioritized, saline implants may be a better choice [15].

With respect to the outcomes of saline implants, deflation, capsular contracture, and consequent distortion of breast shape were common causes of implant removal. Gutowski et al. [16] reported a reoperation rate of 20.6% (104 of 504 patients) between 1980 and 1989. Of these, Implant deflation occurred in 5.5% and significant capsular contracture affected 20.4% of patients, necessitating open capsulectomy for capsular contracture and removal or replacement of a deflated implant. A longer follow-up report by Cunningham et al. [17] revealed an overall complication rate of 20.2%, with a reoperation rate for capsular contracture or deflation of 23.1%.

From a prospective multicenter study of >900 augmentation or reconstruction patients implanted with Natrelle saline breast implants, the 10-year risk rate for implant replacement/removal was 20.2% and 39.5% for augmentation and reconstruction patients,

respectively. The most common reason for implant replacement/removal among augmentation patients was the patient's choice for a style or size change, whereas that among reconstruction patients was deflation [18]. In reconstruction cases, a previous report involving 201 Korean patients showed a deflation rate of 9.4%, and three of the 19 patients with deflation had iatrogenic causes. Deflation was more common in textured implants, and significant capsular contracture was reported in 17% [9].

Although our study included fewer patients than previous studies, we analyzed the long-term outcomes of saline implants and the factors affecting those outcomes over a longer follow-up period. The most common early complications were delayed wound healing (12.2%) and skin necrosis (7.3%), and the common late complications were rippling or visibility (14.6%) and capsular contracture (12.2%). A significant factor influencing early complications was nipple-areola-sparing mastectomy, which seemed to be directly associated with delayed wound healing and skin necrosis. The nipple-areola-sparing technique in the past would have been performed more often by less-experienced surgeons than in the present, which may have resulted in longer operation times and more intense skin traction.

Late complications were defined as those that occurred >90 days postoperatively; their incidence was mainly documented from patient-reported complaints and were often associated with reoperation. The factors influencing late complications were the nipple-areola-sparing technique, patient age, implant fill volume, and implant manufacturer. We assumed that early skin necrosis due to the nipple-areola-sparing procedure would have led to skin contraction or early reoperation, which subsequently would have influenced later shape distortion. The size of the implant has often been reported to be associated with the final outcome; correspondingly, our results did not show a correlation of implant size with early complications (within 90 days), but did show a correlation with late complications (after 90 days). The impact of patient age on late complications and reoperations may be partly explained by the larger implant size in older patients or by asymmetry due to breast ptosis. Another explanation may be the different oncologic status of the patients (the younger the patient, the higher the likelihood of advanced cancer). Oncologic seriousness and the requirement for reoperations due to recurrence often diminished patients' interest in aesthetics.

With respect to the manufacturer, the incidence of late complications was significantly higher for Allergan implants than for Mentor implants. As all our saline implants were smooth round implants, we do not think that this factor was directly related to the high rate of performance failure of Biocell implants, as reported in a recent article that analyzed breast implant explantations and found that Biocell implants were associated with double capsule, late seroma, and pain [19]. Conversely, our results showed that the explanted Allergan implants were more often associated with rip-

pling, visibility, thinning, and/or pain, whereas two of the four Mentor implants were explanted because of malposition.

The absence of prosthesis removal or lack of reoperation in patients with tumor recurrence does not inherently mean that the outcomes, despite tumor ablative operations and radiotherapy because of recurrence, were good. The treatment of patients after breast reconstruction often involves multidisciplinary modalities, including oncologic surgery, oncology, radiation oncology, gynecology/endocrinology, and rehabilitation. Oncologic severity and adjuvant therapies may diminish patients' interest in aesthetic outcomes. The late aesthetic outcomes in the current retrospective study mainly depended on the patients' voluntary and subjective requests, which may explain the lower late elective complication rate in our study than has been reported in the literature. Another point to consider is that direct-to-implant reconstruction was significantly less common than at present. The fewer number of overall reconstructions meant that more autologous reconstructions were performed, and far more strict patient selection criteria were applied for direct-to-implant cases, such as younger age, smaller breasts with less ptosis, and lower clinical cancer stage (less likelihood for adjuvant radiation). This may also explain the lower rate of both early and late complications.

The study has some limitations. Firstly, the sample size is small, and this is not a case-control study. Nevertheless, this study presents the results of long-term follow-up with few dropouts that reflect the real needs of reconstruction patients. Although the use of saline implants is rare in Korea at present, with saline implants having a <4% market share, patients who received saline implants in the past still visit the clinic for consultations. The use of textured anatomic silicone implants has been abruptly discontinued for unexpected reasons, and saline implants may not simply be considered as an obsolete option. Therefore, this study provides useful information for consulting with patients who already have saline implants or those who request information about as many implant options as possible.

Another limitation is that onset of late complications was not classified by the period. Early information on reconstructed patients was collected on paper charts, so some visits due to late complications were not recorded. In addition, the choice of implant was based on each patient's breast width and projection; therefore, no difference in patient characteristics was found according to whether an Allergan or Mentor implant was inserted. Nonetheless, there might be a hidden disturbance variable.

In summary, patients who underwent direct-to-saline implant reconstruction showed an initial complication (within 90 days) rate of 19.5% and a late complication (after 90 days) rate of 29.3%. The most common initial complications were skin necrosis and delayed healing, and the most common late complications were rippling or visibility and capsular contracture. Late complications may have been underestimated because they were mainly based on

patient-reported complaints. Approximately 22% of the implants were replaced (12%) or converted to autologous tissue (10%). The factors that influenced the final outcomes were patient age, a nipple-areola-sparing procedure, breast size and implant fill volume, and implant manufacturer.

NOTES

Conflict of interest

No potential conflict of interest relevant to this article was reported.

Ethical approval

The study was approved by the Institutional Review Board of Asan Medical Center Hospital (IRB No. 2018-0540) and performed in accordance with the principles of the Declaration of Helsinki.

Patient consent

The patient provided written informed consent for the publication and the use of her image.

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